EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

JOSEPH ROWE,	)	
	)	
` *Plaintiff,*	)	Civ. No. 1:15-cv-00173-MCA-SCY
v.	)	
	)	
C. R. BARD, INC., a New Jersey Corporation, BARD PERIPHERAL VASCULAR, INC., (a subsidiary and/or division of defendant C. R. BARD, INC.), an Arizona Corporation	)	
	)	
Defendants.	)	

PLAINTIFF'S FIRST REQUESTS FOR PRODUCTION OF
DOCUMENTS TO DEFENDANT BARD PERIPHERAL VASCULAR, INC.

TO: Defendant Bard Peripheral Vascular, Inc., by and through its attorneys of record, Alex C. Walker and Tiffany L. Roach Martin Modrall, Sperling, Roehl, Harris & Sisk, P.A., 500 Fourth Street NW, Suite 1000, Albuquerque, New Mexico 87102; and Taylor Tapley Daly, Richard B. North, Jr. and Matthew B. Lerner, Nelson, Mullins, Riley & Scarbrough, LLP, 201 17th Street NW, Suite 1700, Atlanta, GA 30363.

Plaintiff, by and through his attorneys of record and pursuant to Federal Rule of Civil Procedure 34, hereby submits the following Requests for Production of Documents to Defendant, BARD PERIPHERAL VASCULAR INC., to be answered within thirty (30) days after service, as follows:

Respectfully submitted,

LAW OFFICES OF BEN C. MARTIN

/s/ Ben C. Martin
Ben C. Martin
Admitted Pro Hac Vice
TX State Bar No. 13052400
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and

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing was sent via First Class Mail this 29th day of July, 2015, to the following:

Alex C. Walker
Tiffany L. Roach Martin
Modrall, Sperling, Roehl, Harris & Sisk, P.A.
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AND

Taylor Tapley Daly, Esq.
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Matthew B. Lerner, Esq.
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Atlanta, GA 30363
Fax: 404-322-6050

/s/ Thomas Wm. Arbon
Thomas Wm. Arbon

DEFINITIONS

The following terms shall have the following meanings, unless the context requires otherwise:

1. "YOU," 'YOUR," or "DEFENDANT" – means Bard Peripheral Vascular, Inc., as well as its divisions, parents, subsidiaries, and each of their present and former officers, directors, employees, agents, and representatives.

2. "ELECTRONIC STORAGE DEVICE" – means any device capable of storing ESI for any period of time, including without limitation disks, including hard disks and floppy disks, CD-ROMS, DVDs, network servers, shared servers, computers, magnetic tape, back-up tape, voice-mail, temporary files, telephones, and PDAs, whether currently on Defendant's premises or otherwise (e.g. at an employee's home or remote office).

3. "ELECTRONICALLY STORED INFORMATION" or "ESI" – means any information stored in an electronic medium, and shall include, without limitation, any information, including files, documents, images, video, metadata or any combination thereof stored, created, or used on any ELECTRONIC STORAGE DEVICE, disk, tape (including backup tapes and other backup media), or other computer or digital storage medium, microfilm, microfiche, floppy, or any other storage or recording medium. ESI include without limitation electronic mail messages, information stored on web pages or web servers, and database records.

4. "RELATE" – or any variant thereof, including, but not limited to, the term "RELATING TO," shall be understood to apply if the data or information evidences, mentions, constitutes, contains, summarizes, describes, concerns, refers to, supports, contradicts, addresses, the subject matter described in this set of demands in which the term "relate," or any variant thereof, appears.

5. "EVIDENCE" – or any variant thereof, including, but not limited to, the term "EVIDENCING," shall be understood to apply if the data or information mentions, discusses, constitutes, concerns, supports, contradicts, or refers to the subject matter described in this set of demands in which the term "EVIDENCE," or any variant thereof, appears.

6. "DOCUMENT" or "DOCUMENTS" – means any handwriting, typewriting, printing, photostating, photographing, photocopying, transmitting by electronic mail or facsimile, and every other means of recording upon any tangible thing, any form of communication or representation, including letters, words, pictures, sounds, or symbols, or combinations thereof, and any record thereby created, regardless of the manner in which the record has been stored; and shall include, without limitation, the original (and absent the original then a copy thereof), all file copies and copies not identical to the original of any writing or record of every type, form, and description that is in the possession, custody, or control of the responding party, or which is no longer is in the responding party's possession but of which the responding party still has knowledge, whether or not said writings or records are claimed to be privileged or otherwise immune from discovery including by way of illustration and not limitation, the following items: notes, correspondence, communications of any nature (including intra-company communications and correspondence), electronic mail messages, telegrams, cables, memoranda (including internal memoranda), notebooks of any nature, including laboratory and engineering reports; summaries, minutes, and records of telephone conversations, personal conversations or interviews; diaries, routing slips or memoranda, reports (including tests and analysis reports), books, manuals, publications, invoices, specifications, shipping papers, purchase orders, flow charts, schematics, diagrams, photographs of any nature, minutes or recordings of any meetings or conferences, including lists of persons attending meetings or conferences; transcripts of oral testimony or statements; labels,

tags, fliers, brochures, pamphlets, advertisements, advertising layouts, circulars, trade letters, press releases, and translations; presentations, including boards, transparencies, storybooks and/or scripts; drafts of original or preliminary notes on, and marginal comments appearing on, an DOCUMENTS; whether those writings or records are on paper, magnetic disk, tape or other computer or digital storage medium, microfilm, floppy, or any other storage media or recording media.

7. COMPLAINT –means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, performance, or malfunction of a device after it is released for distribution.

8. REPORTABLE EVENT – means any information that YOU received or otherwise became aware of, from any source, that YOU believed that YOU were required to report to the Food and Drug Administration because it reasonably suggested that a device that YOU marketed may have caused or contributed to a death or serious injury; or malfunctioned and this device or a similar device that YOU market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

DEMAND FOR FORMAT OF PRODUCTION

9. **Load Files.** Except for ESI described in Paragraphs 13(b) and (c) below, ESI must be produced in electronic format, with files suitable for loading into a Concordance litigation support database. The load files will define document breaks, attachments and other information identified below.

10. **Document Cross-Reference File**. YOU should provide a cross-reference file that identifies the start and end of the document, its attachments and its corresponding metadata.

11. **Cross-Reference or Linking File**. YOU should also provide a cross-reference file that facilitates the linking of the produced image or native file with the litigation database. This cross-reference file will contain fields such as the unique document ID (i.e., beginning bates stamp number)

and the file path of the corresponding image or native file. YOU may provide this information either in a Concordance litigation database format or as a standard delimited ASCII text file.

12. **Categories of Production of ESI**. ESI should be produced as follows, depending on its classification.

a. **Production of ESI AS TIFF Images With Metadata and Extracted Test.** Documents created in standard office automation file formats (including but not limited to Microsoft Word or Word Perfect documents) and ESI that can be practicably converted into TIFF format will be produced as single-page TIFF GROUP IV images, with any available fielded metadata and text searchable information extracted from the native documents.

i. **Bates Numbering.** The producing party will brand all TIFF images in the lower right hand corner with its corresponding Bates number, using a consistent font type and size. The Bates number must not obscure any part of the underlying image.

ii. **File Names.** Image file names will be identical to the corresponding bates numbered images, with a ".tif" file extension.

iii. **Production of Extracted Full Text.** The producing party will provide extracted full text (i.e., text extracted from ESI) for all material originating as ESI in a text file corresponding to a single page of a document. The full text file name will be composed of the Bates number of the associated document, with a ".txt" file extension.

iv. **Production of Metadata**. The producing party will provide the following metadata, as applicable, for all ESI: start Bates, end Bates, start attachment, end attachment, custodian or source, original file path, original file name, file type/file extension, MD-5 hash value, title, creation date, creation time, page count, last modification date, last modification time, and last saved by name.

v. **Metadata for E-mail**. In addition to the metadata to be produced for all ESI, for all e-mail, the producing party will also produce the following as fielded metadata: subject, author, recipients, from, to, copies, blind copies, date sent, time sent, date received, time received, MD-5 hash value, attachment file name, begin attachment, and end attachment. Family relationships among e-mail and attachments will be maintained by ensuring that attachments immediately follow their parent e-mail, and setting the "begin attachment" and "end attachment" metadata fields appropriately.

vi. **Redaction.** If a file that originates in ESI needs to be redacted before production, the file will be rendered in TIFF, and the TIFF will be redacted and produced. However, to the extent that the text is searchable in the native format, the producing party will still provide searchable text for those portions of the document that have not been redacted.

b. **Production of Native Format Documents That Are Impracticable to Convert to TIFF.** ESI that is not practicable to convert to TIFF may be produced using one of the two following methods, which method will be subject to meet and confer between the parties.

i. **Spreadsheets That Are Impracticable to Convert to TIFF.** ESI that is not practicable to convert to TIFF (for example, spreadsheets) may be produced in electronic format suitable for loading to a litigation support database with links to native files.

1. **Identification.** ESI produced in native file format will be assigned a unique DocID number within the litigation database.

2. **File Names.** File names will be identical to the DocID number, followed by the original file name and file extension.

3. **Authentication.** The producing party will provide a litigation database load file with separately fielded data, which will contain, as on of the fields, the MD-5 hash value of each file produced in native format.

ii. **ESI That Is Impractical to Produce With Links to a Database.** For any ESI where linking a native document will render the document unusable, the ESI should be produced in native form, accompanied with a Bates number and MD-5 hash value, but separate from a litigation support database.

c. **Reports in Lieu of Native Production.** If the producing party believes that it would be impracticable to produce ESI in native format because of complexities associated with certain scheduling programs, accounting systems, mapping systems, and/or other databases (such as MS Access, Oracle, and Microsoft SQL Server), it will so notify the propounding party and will inform the propounding party whether it has generated reports in the normal course of business using those programs or systems. In any such instance, the parties will meet and confer concerning the manner of production of those reports.

d. **Production of Pictures/Images.** Any photographic images created and/or maintained in electronic format will be produced in that format.

13. **Production of Media.** The producing party will use the appropriate electronic media (CD, DVD, or hard drive) for its ESI production and will label the physical media with the production date, media volume name, and document number range.

14. **ESI Requiring Proprietary Software.** If proprietary software unavailable to plaintiff is required to review the producing party's ESI in native format, YOU shall provide reasonable access to the proprietary software for purposes of review of ESI by Plaintiffs and any expert or other persons working on behalf of Plaintiff.

REQUEST FOR PRODUCTION OF DOCUMENTS

REQUEST FOR PRODUCTION NO. 1:

Produce in electronic format complete copies of all Databases that YOU used to track, trend and/or record information regarding any COMPLAINT and/or REPORTABLE EVENT that YOU became aware of for the Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter, Meridian and/or the Denali Filter. This request includes, to the extent that the databases incorporate this information, any and all information regarding what the COMPLAINTS or REPORTABLE EVENTS consisted of; when they were received by YOU; what action YOU took in response to the COMPLAINTS; who YOU contacted or communicated with regarding the COMPLAINTS; any follow-up efforts YOU made to obtain further information or the explanted product; if and when YOU and the FDA communicated regarding the COMPLAINTS or REPORTABLE EVENTS; whether the COMPLAINT was in the form of a Medwatch Report, communication from a medical provider or consumer, an Adverse Event Report or other form; what YOUR conclusions were as to each COMPLAINT or REPORTABLE EVENT; and the current status or final disposition of the COMPLAINT or REPORTABLE EVENT.

REQUEST FOR PRODUCTION NO. 2:

Produce copies of each individual complaint file that YOU created and maintained in response to each COMPLAINT YOU became aware of for the Recovery, G2 Filter, G2 Express Filter, Eclipse Filter, Meridian Filter and Denali Filter including all DOCUMENTS and ESI contained therein EVIDENCING or RELATING to what the COMPLAINT consisted of; when it was received by YOU; what action YOU took in response to the COMPLAINT; any communications YOU made or received regarding the COMPLAINT, including internal communications; any follow-up efforts YOU made to obtain further information regarding the COMPLAINT or the explanted product; whether and on what basis YOU decided to not investigate; whether the COMPLAINT was in the form of a Medwatch

Report, communication from a medical provider or consumer, an Adverse Event Report or other form; what YOUR conclusions were as to the COMPLAINT; and the current status or final disposition of the COMPLAINT.

REQUEST FOR PRODUCTION NO. 3:

To the extent not produced in response to the preceding request for production, produce all DOCUMENTS AND ESI EVIDENCING and/or RELATING to the following: any and all COMPLAINTS YOU became aware of for Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter, Meridian Filter and/or Denali Filter, including what the COMPLAINTS consisted of, and when they were received by YOU; what action YOU took, if any, in response to each COMPLAINT regarding the Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter, Meridian Filter and/or Denali Filter, including any attempts to obtain further information from the health care providers who treated the person whom was allegedly injured by the device or had the device malfunction; any communications YOU made or received regarding each COMPLAINT for the Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter, the Meridian Filter and/or Denali Filter, including internal communications; the results of any investigations regarding each COMPLAINT for the Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter, the Meridian Filter and/or Denali Filter and/or the basis for the decision to not investigate; and what YOUR conclusions were as to each COMPLAINT; and the current status or final disposition of the COMPLAINT.

REQUEST FOR PRODUCTION NO. 4:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any COMPLAINTS YOU received for any IVC Filter implanted in Plaintiff, Gary Milton, Sr., including all DOCUMENTS and ESI EVIDENCING or RELATING to what the COMPLAINT consisted of; when it was received by YOU; what action YOU took in response to the COMPLAINT; any and all communications YOU made or received regarding the COMPLAINT, including internal communications; any follow-up efforts YOU made to obtain further information regarding the COMPLAINT or the explanted product; whether and on what basis YOU decided to not investigate; whether the COMPLAINT was in the form of a Medwatch Report, communication from a medical provider or consumer, an Adverse Event Report or other form; what YOUR conclusions were as to the COMPLAINT; and the current status or final disposition of the COMPLAINT.

REQUEST FOR PRODUCTION NO. 5:

Produce copies of each file that YOU established and maintained in response to each individual REPORTABLE EVENT (commonly known as Medical Device Report event files, source files, backup files, or MDR event files, and as required by 21 C.F.R. 803.18) relating to any Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter, Meridian Filter and/or Denali Filter, including all DOCUMENTS and ESI contained therein EVIDENCING or RELATING to any and all information in YOUR possession or references to information in YOUR possession related to the underlying COMPLAINT, any attempts YOU made to communicate with anyone to gather further information regarding the COMPLAINT or to obtain the explanted product itself, any analysis or evaluation YOU conducted of the explanted device or similar devices, YOUR deliberations and decision-making processes used to determine whether the COMPLAINT was or was not a REPORTABLE EVENT, any investigations YOU conducted to determine the cause of the event, and copies of all medical device

report forms, including supplemental reports, and other information submitted to the Food and Drug Administration.

REQUEST FOR PRODUCTION NO. 6:

To the extent not produced in response to the preceding request for production, produce all DOCUMENTS AND ESI EVIDENCING or RELATING to the following information for each individual REPORTABLE EVENT for any Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter, Meridian Filter and/or Denali Filter:

a. any information in YOUR possession or references to information in YOUR possession related to the REPORTABLE EVENT;

b. any attempts YOU made to communicate with anyone to gather further information regarding the COMPLAINT or to obtain the explanted product itself;

c. any communications YOU made or received, including internal communications, regarding the REPORTABLE EVENT;

d. whether the explanted device was available for testing, and any analysis, testing, or evaluation YOU conducted of the explanted device or similar devices;

e. Any description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient follow-up or required treatment, and any environmental conditions that may have influenced the event;

f. YOUR deliberations and decision-making processes used to determine whether the COMPLAINT was or was not a REPORTABLE EVENT;

g. any investigations YOU conducted to determine the cause of the event; and

h. any action YOU took as a result of the REPORTABLE EVENT to prevent recurrence of the REPORTABLE EVENT.

i. copies of all medical device report forms, including supplemental reports, and other information submitted to the Food and Drug Administration

REQUEST FOR PRODUCTION NO. 7:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any REPORTABLE EVENT regarding a Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter, Meridian Filter and/or the Denali Filter that YOU submitted to the Food and Drug Administration because YOU determined that the COMPLAINT necessitated remedial action to prevent an unreasonable risk of substantial harm to the public health, or because the Food and Drug Administration made a written request for the submission of 5-day report pursuant to 21 C.F.R. 803.53.

REQUEST FOR PRODUCTION NO. 8:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any request by the Food and Drug Administration for YOU to conduct post-market surveillance of the Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter System, Meridian Filter or Denali Filter; and any plans, reports, or other information YOU submitted to the Food and Drug Administration in response.

REQUEST FOR PRODUCTION NO.9

Produce all DOCUMENTS AND ESI EVIDENCING or referring to any and all data analysis or trends of adverse events that were reported to YOU regarding the Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter, Meridian Filter and/or the Denali Filter, including any studies, research or documents prepared to reflect any analysis or trend.

REQUEST FOR PRODUCTION NO.10

Produce all DOCUMENTS AND ESI EVIDENCING or referring to any and all written procedures or standards YOU had in place at the time YOU first began to market or distribute the Recovery Filter regarding receiving, reviewing, investigating, evaluating, and/or documenting COMPLAINTS YOU received for devices that YOU marketed or distributed, including the Recovery Filter. This includes for example, any questionnaires or follow-up procedure YOU developed to deal with specific types of device failures such as where an IVC Filer reportedly migrates away from the location it was originally implanted.

REQUEST FOR PRODUCTION NO. 11:

Produce all DOCUMENTS AND ESI EVIDENCING or referring to any and all changes or additions to the procedures and standards identified above, including any changes made specifically regarding the Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter. Meridian Filter and Denali Filter up until April 25, 2010. This demand includes for example, any questionnaires or follow-up procedure YOU developed to deal with specific types of device failures such as where an IVC Filer reportedly migrates away from the location it was originally implanted.

REQUEST FOR PRODUCTION NO. 12:

Produce all DOCUMENTS AND ESI EVIDENCING any and all written procedures or standards YOU had in place in January 2003 regarding the timely identification, communication, investigation, and evaluation of COMPLAINTS that may constitute REPORTABLE EVENTS; the review process for determining when a COMPLAINT meets the criteria for being a REPORTABLE EVENT; the documentation and recordkeeping requirements for information YOU evaluated to determine whether COMPLAINTS YOU received constituted REPORTABLE EVENTS, the documentation and recordkeeping requirements for all REPORTABLE EVENTS and information

related thereto actually submitted to the FDA; and the documentation and recordkeeping requirements regarding any information that was evaluated for the purpose of preparing the submission of annual reports.

REQUEST FOR PRODUCTION NO. 13:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any and/or all changes or additions YOU made to the procedures and standards identified in the preceding request for production from January 2003 to today.

REQUEST FOR PRODUCTION NO. 14:

To the extent not already produced, produce all DOCUMENTS AND ESI EVIDENCING or referring to any information provided to any of YOUR employees or agents; who were responsible for following up with or communicating with health care providers regarding adverse events associated with the Recovery Filter, G2 Filter, G2 Express Filter; the Eclipse Filter, the Meridian and/or Denali regarding the following: the potential or known ways in which these devices could fail, the known or suspected failure rates of these devices, any information that these persons were to communicate to and/or obtain from the health care provider(s), and any training materials, scripts, questionnaires, and instructions that were to guide interactions with health care providers regarding adverse events for these devices.

REQUEST FOR PRODUCTION NO. 15:

Produce all DOCUMENTS AND ESI EVIDENCING any and/or all written procedures or standards YOU had in place in January 2003 regarding establishing and maintaining files for each REPORTABLE EVENT (otherwise known as Medical Device Report event file or MDR event files) that would contain any and/or all information in YOUR possession or references to information in YOUR possession related to the underlying COMPLAINT, including all documentation of YOUR deliberations and decision-making processes used to determine if a device-related death serious injury, or malfunction was or was not a REPORTABLE EVENT, and copies of all medical device report forms and other information submitted to the Food and Drug Administration.

REQUEST FOR PRODUCTION NO. 16:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any and/or all changes or additions YOU made to the procedures and standards identified in the preceding request for production from January 2003 through to today.

REQUEST FOR PRODUCTION NO. REQUEST NO. 17:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to communications and/or correspondence known as “Dear Doctor” or “Dear Healthcare Professional” letters prepared, generated, authored, and/or sent by YOU to health care professionals, including physicians, hospitals, and clinics, in the United States and other countries, including any and all preliminary and final drafts of such letters, all minutes from company or directors meetings in which revisions or amendments to such communications and letters were discussed, as well as all editions or notations made by YOU, concerning the Recovery Filter, G2 Filter or G2 Express Filter.

REQUEST NO. 18:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING any communications whether by e-mail, telephone, facsimile, or verbal between YOU and Plaintiff Joseph Rowe's health care providers including Kevin Williams, MD and The University of New Mexico Health Science Center, in Albuquerque, New Mexico regarding the safety and/or efficacy of the Recovery Filter, G2 Filter, G2 Express Filter and/or Eclipse Filter.

REQUEST NO. 19:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any advertising, marketing, and/or promotional material concerning the Recovery Filter, G2 Filter, G2 Express Filter, Eclipse Filter, Meridian Filter, or Denali Filter, including ads in medical journals, publications, and periodicals, detail brochures, mailings, literature, pamphlets, PowerPoint slides, group presentations given at public, semi-public, and/or private medical-related professional organization meetings, seminars, and/or conventions, undertaken and/or provided by YOU to Plaintiff Joseph Rowe's health care providers including Kevin Williams, MD and the University of New Mexico Health Science Center, in Albuquerque, New Mexico.

REQUEST NO. 20:

Produce 5 exemplars of the Recovery Filter.

REQUEST NO. 21:

Produce 5 exemplars of the G2 Filter.

REQUEST NO. 22:

Produce 5 exemplars of the G2 Express Filter.

REQUEST NO. 23:

Produce 5 exemplars of the Eclipse Filter.

REQUEST NO. 24:

Produce 5 exemplars of the Meridian Filter.

REQUEST NO. 25:

Produce 5 exemplars of the Denali Filter.

REQUEST NO. 26:

For all other cases, whether resolved or ongoing, in which a Recovery Filter, G2 Filter, G2 Express and/or Eclipse Filter is or was alleged have fractured, migrated, and/or perforated the vena cava, please produce copies of deposition transcripts and deposition videos of all past and present employees, officer, directors, or agents of C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc., who were deposed in said actions.

REQUEST NO. 27:

For each deposition transcript and/or deposition video that YOU produce in Response to Request for Production No. 26 above, please also produce copies of all exhibits that were used at each corresponding deposition. (Please note that private information of other plaintiffs or injuries parties may be redacted).

REQUEST NO. 28:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to Bard's estimations as to the complication rates for each of its IVC filters, i.e, the Recovery, G2, G2 Express, G2X, Eclipse Meridian and Denali, utilizing "the comprehensive process for estimating the complication rates of its own devices" that "relies on multiple sources beyond the MAUDE database, including, but not limited to, customer complaints, medical literature, physician input, and sales representatives' observations," the Defendant has alleged in use. This request includes the all the underlying data, customer complaints, medical literature, physician input, sales representatives' observations, government agency information such as MAUDE data, calculations, assumptions, and reference materials used to produce the estimations as well as the results and conclusions reached regarding each of Bard's IVC filter models.

REQUEST NO. 29:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any and all comparative failure rate analyses and attempts to compare the rate of failure for each of Bard's IVC filters models, i.e, the Recovery, G2, G2 Express, G2X, Eclipse Meridian and Denali to the failure rates of Bard's competitors' IVC filters. This request specifically includes all the underlying data, customer complaints, medical literature, physician input, sales representatives' observations, government agency information such as MAUDE data, calculations, assumptions and reference materials used to produce the estimations as well as the results and conclusions reached regarding each of Bard's IVC filter models.

REQUEST NO. 30:

Produce a true, correct and complete copy of the report from Dr. John Lehmann to comparing the failure rate of the Recovery filter to its competitors and all DOCUMENTS AND ESI EVIDENCING or RELATING to the data, customer complaints, MAUDE data, calculations, assumptions and reference materials used to create the report.

REQUEST NO. 31:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to Design History File ("DHF") for the Eclipse IVC Filter including surgeon discussions, prototypes, design input, design output, design review, design verification, design validation, design transfer and design changes.

REQUEST NO. 32:

Produce all DOCUMENTS and ESI of all documents relating to the design, manufacture, and engineering of the Eclipse IVC Filter, including, but not limited to, the following:

a. Any differences in the manufacturing processes regarding different generations, models, or versions of the Eclipse IVC Filter;

b. All plans, designs, and prototypes for the Eclipse IVC Filter;

c. All documents relating to changes at any time in the design, specifications, manufacture, and procedures for the manufacture of the Eclipse IVC Filter, including changes to its materials, component parts, composition and construction;

d. All complete engineering drawing packages, engineering drawings, specifications, requests for changes, and change notices; and

e. All engineering reports or evaluations of each version of the Eclipse IVC Filter.

REQUEST NO. 33:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any and all correspondence, intra-office memoranda, reports, summaries, or other written or recorded items sent to or received from the FDA or any other industry consumer or federal organization or agency pertaining to the Eclipse IVC Filter.

REQUEST NO. 34:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to all claims and notices of complaints and inquiries related to injuries or defects associated with the Eclipse Filter from January 14, 2010 to the present.

REQUEST NO. 35:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to any tests, analyses, and evaluations of the Eclipse IVC, including all results and conclusions of any testing facility, and all responses by you to the testing facility. This request includes, hut is not limited to, documents related to:

a. Testing or certification to determine if the Eclipse IVC Filter meets or fails to meet any mandatory or voluntary standard, Bard's design specifications and/or Bard's performance goals;

b. All testing to evaluate the safety of the Eclipse IVC Filter, including but not limited to fatigue trials, mechanical analysis, finite element analysis, clinical studies and/or animal testing;

c. Testing to assess how a consumer will interact with and operate the Eclipse IVC Filter, including any human behavior analysis whether by a Human Factors expert or any other expert or person;

d. Testing and analysis related to age and weight grading the Eclipse IVC Filter;

e. All documents related to any changes made in the design, manufacture, importation, distribution, sale, marketing, promotion, or advertising of the Eclipse IVC Filter based on any tests, analyses, and evaluations of the Eclipse IVC Filter.

REQUEST NO. 36:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to the advertising, marketing, and promotion of the Eclipse IVC Filter, including all changes in the marketing and promotion strategy, or in the advertisements, for the Eclipse IVC Filter. This request includes, but is not limited to, documents related to:

a. Any research and analysis of competitive products;

b. Any analysis of the pricing of the Eclipse IVC Filter:

c. Any advertising, marketing, and promotion of the Eclipse IVC Filter, including, but not limited to, that which appeared online, on the radio, in newspapers and magazines, or on television. Included in this request is any advertising, marketing, promotion, or product giveaways appearing on the Internet, including on any blogs or social media sites. Also included in this request are signs, brochures, direct mailings, email messages, and advertising, marketing, and promotion in retail stores and directed to retail customers;

d. Any special offers related to the Eclipse IVC Filter, including any discounts, sales, free products, or other incentives to retail customers or other consumers to purchase or promote the Eclipse IVC Filter.; and

e. Any public relations designed to promote, or related to the sale of, the Eclipse IVC Filter.

REQUEST NO. 37:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to the warnings and instructions for use that accompanied the Eclipse IVC Filter and any revisions of those warnings and instructions, including all such materials related to the testing or analysis of the effectiveness of the warnings and/or users compliance with the warnings and instructions.

REQUEST NO. 38:

A true, correct and complete copy of the Instructions for Use that would have accompanied the Eclipse IVC Filter implanted in the Plaintiff on May 6, 2011.

REQUEST NO. 39:

A true, correct and complete copy of the observations noted on Form FDA 483s, Lists of Inspectional Observations that were issued to you at the close of the FDA's inspections that are referenced in the warning letter issued by FDA on July 13, 2015 .

REQUEST NO. 40:

True, correct and complete copies of the complaint files referenced in paragraph 3(b) of the warning letter issued by FDA on July 13, 2015.

REQUEST NO. 40:

True, correct and complete copies of all communications sent to or received from the FDA related to the subject matter of the warning letter issued by the FDA on July 13, 2015.

REQUEST NO. 41:

True, correct and complete copies of any and all regulatory logs of contacts with the FDA regarding the warning letter issued by FDA on July 13, 2015.

REQUEST NO. 42:

Produce all DOCUMENTS AND ESI EVIDENCING or RELATING to internal communications relating to the subject matter of the warning letter issued by FDA on July 13, 2015.